

Escherichia coli O157 Test

1. INTENDED USE

Escherichia coli O157 Test is a sandwich lateral flow immunochromatographic assay for the qualitative detection of Escherichia coli O157 in food.

LOD: 1 X 10⁵ cfu/mL

Assay Time: 10 - 15 min

2. PRINCIPLE OF THE ASSAY

Escherichia coli O157 Test is based on sandwich lateral flow immunochromatographic assay. The test device has a testing window. The testing window has an invisible T (test) zone and C (control) zone. When sample is applied into the sample hole on the device, the liquid will laterally flow on the surface of the test strip. If there is enough Escherichia coli O157 in the sample, a visible T band will appear. The C band should always appear after a sample is applied, indicating a valid result. By this means, the device can accurately indicate the presence of Escherichia coli O157 in the sample.

3. KIT COMPONENT

- 10 X foil pouches, each containing one cassette, one pipette and a desiccant
- Product Manual

4. TEST PROCEDURE

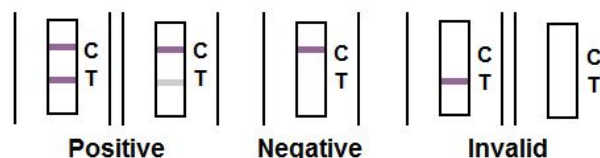
- Incubation. Incubate the pre-enrich sample with enrichment broth, according to FDA suggested method or other well-established incubation method.
- Transfer 2 mL of incubated sample broth into a glass tube and boil for 10 minutes. Cool the samples to room temperature.
- Take out the cassette from the foil pouch and place it horizontally.
- Suck the boiled sample broth and drip 3 drops into the assay sample hole "S".
- Interpret the result after 10 minutes. Result after 15 minutes is considered as invalid.

5. INTERPRETATION OF RESULTS

Positive: The presence of both C band and T band, no matter T band is clear or vague.

Negative: Only clear C band appears.

Invalid: No colored band appears in C zone, no matter whether T band appears.



6. STORAGE

The kit can be stored at room temperature (2-30°C). The test kit is stable through the expiration date (18 months) marked on the foil pouch. **DO NOT FREEZE.** Do not store the test kit in direct sunlight.

7. PRECAUTIONS

- For best results, please strictly adhere to these instructions.
- All reagents must be at room temperature before running the assay.
- Do not remove test cassette from its pouch until immediately before use.
- Do not reuse the test kit.
- Do not use the test beyond its expiration date marked on the foil pouch.
- The components in this kit have been quality control tested as standard batch unit. Do not mix components from different lot numbers.

8. LIMITATION

Escherichia coli O157 Test is for in vitro testing only. For an accurate result, It is suggested to apply other method such as PCR for final determination in practice.